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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,313	05/21/1999	RAM PRATAP	U-012254-3	7625
140	7590	02/28/2006	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			BALLS, ROBERT J	
			ART UNIT	PAPER NUMBER

1625

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/316,313	PRATAP ET AL.	
	Examiner	Art Unit	
	James Balls	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 23-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 11-18 and 23-32 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 11 - 18, and 23 - 32 are rejected under 35 U.S.C. §103 as being unpatentable over Nodiff (US Pat. No. 5,104,885) in view of *Paliwal et al.* (Journal of chromatography, 616:155-160 (1993)) and *Puri et al.* (Am J. Trop. Med. Hyg., 41(6):638-42(1989)). As explained in the previous action, Nodiff discloses primaquine as a curative anti-malarial drug. *Paliwal et al.* teaches that CDR1 80/53, a primaquine prodrug, has similar anti-malarial activity but is much less toxic than primaquine. *Puri et al.* found the curative dose of CDR1 80/53 as 1.25 mg/kg per day for 7 days (page 638, Experimental groups). Applicants claim the primaquine prodrug CDR1 80/53 at a dose of "not more than 1.0 mg/kg of body weight per day" in Claims 11-15, 23, and 31, and claim the primaquine prodrug CDR1 80/53 at a dose of "not more than 5.0 mg/kg of body weight" in claims 16 -18, 24 - 30 and 32. The only difference between the prior art and applicant's claims is the dosage concentration. Mere differences in concentration will not support the patentability of subject matter encompassed by the

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prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPTQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997); MPEP 2144.05 (Obviousness of Ranges, II. Optimization of Ranges). The invention, as claimed, is unpatentable because applicants have merely adjusted dosage concentrations of known methods, i.e. inhibiting the transmission of malaria by administering an effective amount of CDR1 80/53.

Claim Rejections - 35 USC § 112, First Paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11 -15 and 23 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants point to Table IV on page 22 as support for claimed dosages. Page 16 of the specification explains Table IV. Applicants point out that the “curative dose” referred to on page 16 explaining the values of Table IV on page 22 refers to “antirelapse curative dosages.” However, the current claims are not restricted to antirelapse curative dosages but read on all methods for inhibiting transmission of malaria. Furthermore, the specification’s explanation (page 16) of Table IV (page 22) is inconsistent with applicants’ explanation of Table IV. Page 16 describes Group V of Table IV as the “Vehicle Control Group,” which “showed marginal fluctuation of Met-Hb level within the normal limits.” Applicants, however, allege that Group V of Table IV provides support for a claim of 1.0mg/kg dose. Therefore, the claims contain subject matter, which is not described in the specification in such a way as to convey that inventors has possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 112, First Paragraph (Enablement)

4. Applicants’ arguments regarding the enablement rejection of Claims 11-15 and 23 have been carefully considered but ultimately deemed unpersuasive. Therefore, Claims 11 - 15 and 23 remained rejected under 35 U.S.C. §112, first paragraph for the reasons set forth in the previous action.

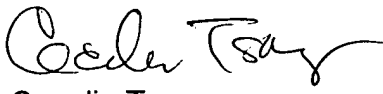
Conclusion

5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Balls
Art Unit 1625
February 7, 2006


Cecelia Tsang
Supervisory Patent Examiner
Art Unit 1625
